

Applicant : Lev Korzinov et al.
Serial No. : 10/781,045
Filed : February 17, 2004
Page : 8 of 14

Attorney's Docket No.: 16491-029001

REMARKS

Claims 1-34 are pending in this application, with Claims 1, 11, 20, 28 and 32 being independent. Claims 29-31 have been amended. No new matter has been added. Reconsideration and allowance of the above-referenced application are requested.

CLAIM OBJECTIONS & CLAIM REJECTIONS UNDER § 112

Claims 29-31 stand objected to for informalities. This objection has been obviated by the present amendment.

Claims 9, 18, 27, 29 and 33 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. This contention is respectfully traversed.

With respect to claims 9, 18, 27 and 29, systems and techniques for signal morphology analysis are well known in the art, and the description in the present application is sufficient to enable one skilled in the art to develop a device as claimed. The following search, “‘t wave’ and (ttl/‘signal morphology’ or abst/‘signal morphology’)”, of the U.S. Patent & Trademark website resulted in two patents: U.S. 5,871,507 and U.S. 5,273,049. Both of these U.S. Patents were filed well before the present application, and both describe signal morphology analysis in their background section as being well known technology. Moreover, signal morphology analyzers are included in various commercially available products, such as the Century Series™ Holter Scanner System, Model C3000/C2000/C1000 manufactured by Biomedical Systems Corporation of St. Louis, MO. Thus, one skilled in the art would be able to implement the subject matter of claims 9, 18, 27 and 29 without undue experimentation.

Furthermore, a prima facie case of lack of enablement has not been established because the current rejection fails to include an undue experimentation analysis and fails to use the factors set forth in *In re Wands*. (See MPEP at §§ 706.03(a) and 2164-2164.08(c).) “Where a major technical rejection is proper, it should be stated with a full development of reasons rather than by a mere conclusion coupled with some stereotyped expression.” (See MPEP at § 707.07(g).) In view of the above, the description of signal morphology analysis in paragraphs

Applicant : Lev Korzinov et al.
Serial No. : 10/781,045
Filed : February 17, 2004
Page : 9 of 14

Attorney's Docket No.: 16491-029001

20, 25 and 26 of the present application, and the description of the T wave morphology in the present application, withdrawal of the rejection of claims 9, 18, 27 and 29 under 35 U.S.C. §112 is requested.

With respect to claim 33, the specification shows and describes in detail various examples of means for alerting a system operator of a possible abnormal T wave, in connection with Figures 1 and 2. For example, the means for alerting can include the communications interface 270 of Figure 2. Moreover, the means for alerting can include the communications channel 130 and the monitoring station 140. In view of this, withdrawal of the rejection of claim 33 under 35 U.S.C. §112 is requested.

CLAIM REJECTIONS UNDER §§ 102(B) AND 103(A)

Claims 1-4, 11, 20, 28, 32 and 34 stand rejected under 35 USC § 102(b) as allegedly being anticipated by Cole et al. (US 4,887,609). Claims 1, 3, 4, 8 and 10 stand rejected under 35 USC § 102(b) as allegedly being anticipated by Schmidt et al. (US 6,167,258). Claim 2 stands rejected under 35 USC § 103(a) as allegedly being unpatentable over Schmidt in view of Cole. Claims 12, 13, 17, 21, 22, 23 and 30 stand rejected under 35 USC § 103(a) as allegedly being unpatentable over Cole in view of Schmidt. Claims 5, 6, 7, 14, 16, 24, 25 and 26 stand rejected under 35 USC § 103(a) as allegedly being unpatentable over Cole. Claim 31 stands rejected under 35 USC § 103(a) as allegedly being unpatentable over Cole. These contentions are respectfully traversed.

Cole describes an electrocardiograph (ECG) filtering apparatus and method in which an ECG signal is filtered to remove unwanted signals, such as contamination signals produced by the use of a nuclear magnetic resonance imaging (MRI) system or muscle artifact signals. (See Cole at Abstract.) Cole does not describe T wave filtering, nor does Cole describe selective use of T wave filtering. Despite this, the Official Action states that the variable filter of Cole could be used as a T wave filter. (See Official Action at pages 4-5.) This contention is unsupported by the record.

Applicant : Lev Korzinov et al.
Serial No. : 10/781,045
Filed : February 17, 2004
Page : 10 of 14

Attorney's Docket No.: 16491-029001

Cole makes very clear that his variable filter is designed to filter out high frequency noise, is always on, and alternates between two filtering states in response to a noise-level indicating signal (e.g., a signal indicating MRI equipment is in use). In the first state, the variable filter "acts as a fifty (50) Hz low pass filter"; and in the second state, the variable filter "acts as a five (5) Hz low pass filter". (See Cole at col. 4, line 36 to col. 5, line 5.) Cole's filter reduces signal amplitude at high frequencies, but let the signal pass at low frequencies. This is in fact the opposite of T wave filtering. Thus, one skilled in the art would clearly understand that Cole's filter cannot be used for T wave filtering, and in no way teaches or suggests selective use of T wave filtering.

Schmidt describes a programmable wireless data acquisition system. As recited in Schmidt's Abstract:

A programmable wireless data acquisition system, comprising a transmitting device and a receiving device. The transmitting device is capable of receiving multiple external inputs and generating and transmitting a radio frequency signal encoded with data corresponding to the inputs. The transmitting device is variably configurable to enable it to accept inputs having different characteristics and ranges and to enable it to provide variable sampling rate, gain and filtering of the inputs. The transmitting device having a microprocessor such that the microprocessor controls the operation thereof. The receiving device is capable of receiving the radio frequency signal, demodulating it and decoding the data. The receiving device has a microprocessor such that the microprocessor controls the operation thereof. External programming device programs the transmitting device and the receiving device by wired connection or through radio frequency signal.

(See Schmidt at Abstract.)

Schmidt describes signal processing hardware that is reconfigurable for different applications. (See Schmidt at col. 8, lines 9-65.) Schmidt describes various kinds of filters, including a prefilter 223 to reject inputs that are outside of a frequency band of interest, an AC (Alternating Current) coupling high pass filter 225 to reject the DC (Direct Current) offset or steady state value of an external input, an antialias low pass filter 226 to guard against false

Applicant : Lev Korzinov et al.
Serial No. : 10/781,045
Filed : February 17, 2004
Page : 11 of 14

Attorney's Docket No.: 16491-029001

signals caused by aliasing between the external input content and the sampling rate of downstream sampling functions, and a digital filter 243 to reject certain portions of the digital data stream to provide an effective decrease in resolution. (See Schmidt at col. 9, line 60 to col. 10, line 14; col. 10, line 34 to col. 11, line 10; and col. 12, lines 17-48.) None of these described filters perform T wave filtering, or can be considered a T wave filter, as claimed. Schmidt does not describe T wave filtering, and in no way teaches or suggests selective use of T wave filtering.

The art of record fails to teach or suggest the subject matter of independent claim 1, including:

identifying heart beats in a sensed cardiac signal;

activating a T wave filter, used in said identifying heart beats, in response to a message from a monitoring station generated at least in part based upon discovery of a predetermined characteristic in the sensed cardiac signal; and

outputting information corresponding to the identified heart beats to a communications channel of a distributed cardiac activity monitoring system.

(See claim 1; emphasis added.)

The art of record fails to teach or suggest the subject matter of independent claim 11, including:

a monitoring apparatus including a communications interface, a real-time QRS detector, a T wave filter, and a selector that activates the T wave filter with respect to the real-time QRS detector in response to a message, wherein the activated T wave filter preprocesses a cardiac signal provided to the real-time QRS detector; and

a monitoring station that communicatively couples with the monitoring apparatus via the communications interface and transmits the message to the monitoring apparatus to activate the T wave filter based at least in part upon a predetermined criteria.

(See claim 11; emphasis added.)

The art of record fails to teach or suggest the subject matter of independent claim 20, including:

a communications interface;

Applicant : Lev Korzinov et al.
Serial No. : 10/781,045
Filed : February 17, 2004
Page : 12 of 14

Attorney's Docket No.: 16491-029001

a real-time heart beat detector;

a T wave filter; and

a selector that activates the T wave filter with respect to the real-time heart beat detector in response to a message, wherein the activated T wave filter preprocesses a cardiac signal provided to the real-time heart beat detector.

(See claim 20; emphasis added.)

The art of record fails to teach or suggest the subject matter of independent claim 28, including:

receiving at least a portion of a sensed cardiac signal from a monitoring apparatus in contact with a living being under active cardiac monitoring;

identify an abnormal T wave in the received cardiac signal; and

sending a message to the monitoring apparatus over a communications channel, the message causing the monitoring apparatus to activate a T wave filter used in identifying heart beats of the living being under active cardiac monitoring.

(See claim 28; emphasis added.)

The art of record fails to teach or suggest the subject matter of independent claim 32, including:

means for identifying heart beats in a sensed cardiac signal;

means for filtering the sensed cardiac signal to reduce T waves in the sensed cardiac signal; and

means for selectively activating the means for filtering in response to discovery of a predetermined characteristic in the sensed cardiac signal.

(See claim 32; emphasis added.)

For all of these reasons, independent claims 1, 11, 20, 28 and 32, and all of their dependent claims, are patentable over Cole and Schmidt. Thus, the rejections based on Cole and Schmidt should be withdrawn for at least the above reasons.

Furthermore, dependent claims 2-10, 12-19, 21-27, 29-31 and 33-34 should also be patentable based on their own merits. For example, with respect to claim 10, the Official Action

Applicant : Lev Korzinov et al.
Serial No. : 10/781,045
Filed : February 17, 2004
Page : 13 of 14

Attorney's Docket No.: 16491-029001

misstates the claim language, and the cited portion of Schmidt does not describe deactivating a T wave filter in response to a message. (See Official Action at page 7.) With respect to claims 5-7, 14-16 and 24-26, the Official Action has improperly misstated the summarized holding of *In re Aller* by leaving out the "by routine experimentation" portion:

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.)

(See MPEP at § 2144.05(II)(A); see the Official Action at page 10.) A prima facie case of obviousness has not been established for any of claims 5-7, 14-16 and 24-26 because (1) neither Cole nor Schmidt describe selective T wave filtering and thus the general conditions of the claims have not been disclosed in the prior art, and (2) no evidence has been provided that modifying the frequency response of a T wave filter as claimed represents "routine experimentation". It should be readily appreciated that, since Cole describes a low pass filter designed to reduce signal amplitude at high frequencies (e.g., reduction of MRI induced noise), no amount of routine experimentation would change Cole's filter into a T wave filter, as claimed.

Moreover, the Official Action frequently makes broad assertions regarding the capabilities of various components mentioned in the cited references, without providing evidentiary support for such statements, as required. For example, with respect to claims 3 and 4, the Official Action asserts various capabilities of "[a]ny ECG monitor" and "any filter" without providing evidentiary support. Attention is called to *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002), in which the Federal Circuit vacated a Patent Office Board affirmance of an obviousness rejection because, rather than relying on objective evidence, the Patent Office based its obviousness rejection on conclusory statements having no evidentiary support in the record. *Id.*

Applicant : Lev Korzinov et al.
Serial No. : 10/781,045
Filed : February 17, 2004
Page : 14 of 14

Attorney's Docket No.: 16491-029001

at 1342-43. In doing so, the Federal Circuit made it abundantly clear that "subjective belief and unknown authority" and "[assertions of] common knowledge and common sense" are not "a substitute for evidence." *Id.* at 1343-44.

CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific issue or comment does not signify agreement with or concession of that issue or comment. Because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

It is respectfully suggested for all of these reasons, that the current rejection is totally overcome; that none of the cited art teaches or suggests the subject matter of the pending claims, and therefore that all of these claims should be in condition for allowance. A formal notice of allowance is thus respectfully requested.

Please apply any necessary charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: Dec. 22, 2005


William E. Hunter
Reg. No. 47,671

Fish & Richardson P.C.
PTO Customer Number 20985
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

10556732.doc